GUIDANT

OCT 2 8 2002

K023300

7. 510(K) SUMMARY

Submitter's Name:	Guidant Corporation CRM Division
Submitter's Address:	4100 Hamline Avenue Mail Stop F330 St. Paul, Minnesota 55112
Telephone: **Fax:**	(651) 582-6691 (651) 582-5134
Contact Person:	Janell A. Colley
Date Prepared:	October 1, 2002
Device Trade Name:	HI-TORQUE® WHISPER™ LS (Light Support) Guide Wire with Hydrocoat Hydrophilic Coating, Model **6726** HI-TORQUE® WHISPER™ MS (Medium Support) Guide Wire with Hydrocoat Hydrophilic Coating, Model **6737** HI-TORQUE® WHISPER™ MS CS-J (Medium Support Coronary Sinus J) Guide Wire with Hydrocoat Hydrophilic Coating, Model **6738** HI-TORQUE® WHISPER™ ES (Extra Support) Guide Wire with Hydrocoat Hydrophilic Coating, Model **4482** HI-TORQUE® WHISPER™ ES CS-J (Extra Support Coronary Sinus J) Guide Wire with Hydrocoat Hydrophilic Coating, Model **4483**
Device Common Name:	Guide Wire
Device Classification Name:	Catheter Guide Wire
Device Classification:	Class II

Summary of Substantial Equivalence:
The design, materials, method of delivery and intended use features of the HI-TORQUE WHISPER LS, MS, ES, MS CS-J, and ES CS-J Guide Wires are substantially equivalent with regard to these features in their predicate device, the HI-TORQUE WHISPER Guide Wires (K020340/March 1, 2002, and K021285/May 2, 2002).

Device Description:
The general guide wire design consists of a stainless steel tapered core with a flexible tip, jacketed by polyurethane on the distal portion of the wire and polytetrafluoroethylene (PTFE) on the proximal portion of the wire. The polyurethane is subsequently covered with a hydrophilic coating to increase lubricity. The guide wires are available with either a straight distal tip that is shapeable, or as a pre-formed 'J' distal tip shaped specifically for accessing the coronary sinus (designated 'CS-J'). The straight tip can be manually shaped to accommodate specific patient anatomy or physician preference; the CS-J shape provides the convenience of an existing 'J' shape without manual shaping.

The HI-TORQUE WHISPER LS, MS/MS CS-J and ES/ES CS-J guide wires with Hydrocoat hydrophilic coating are guide wires with a 0.014" maximum diameter and a length of 190 cm. These wires are constructed with a high tensile (Hyten) stainless steel core wire having a nominal diameter of 0.0128" (LS/MS versions) or 0.0132" (ES versions). The distal segment of each guide wire consists of a series of unique tapers and grinds which reduce the diameter and support at the distal core, thus yielding the desired flexibility and performance characteristics.

Intended Use:
The HI-TORQUE WHISPER Guide Wire is intended to aid in the placement of a Guidant implantable coronary venous lead in the coronary venous vasculature.

Technological Characteristics:
Comparisons of the proposed and predicate device show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed device.

Performance Data:
The results of the verification testing demonstrate that the HI-TORQUE WHISPER LS, MS, ES, MS CS-J, and ES CS-J Guide Wires meet the established acceptance criteria and perform in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program.

Conclusions:
The Guidant CRM HI-TORQUE WHISPER LS, MS, ES, MS CS-J, and ES CS-J Guide Wires have the same intended use, materials, technological characteristics, performance properties, and use identical sterilization processes as the Guidant VI Whisper LS and MS (Enhanced Radiopacity) guidewires and the Guidant CRM HI-TORQUE guidewires; therefore, there are no new safety or effectiveness issues. The modified HI-TORQUE WHISPER Guide Wires are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2002

Guidant Corporation
c/o Ms. Janell A. Colley
Regulatory Affairs Associate
Cardiac Rhythm Management
4100 Hamline North
St. Paul, MN 55112-5798

Re: K023300
Trade Name: Hi-Torque Whisper LS, MS, MS CS-J, ES, and ES CS-J Guide Wires with Hydrocoat Hydrophilic Coating
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: October 1, 2002
Received: October 3, 2002

Dear Ms. Colley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

510(k) Number (if known)

Device Name HI-TORQUE WHISPER LS, MS, MS CS-J, ES, and ES CS-J Guide Wires with Hydrocoat Hydrophilic Coating

Indications for Use The HI-TORQUE WHISPER Guide Wire is intended to aid in the placement of a Guidant implantable coronary venous lead in the coronary venous vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023300

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)